UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA

IN RE: ACTOS (PIOGLITAZONE) PRODUCTS LIABILITY LITIGATION	**6:11-md-2299**
THIS DOCUMENT APPLIES TO:	JUDGE DOHERTY
***DeJesus v. Takeda, et al.*, 6:12-cv-00781**	MAGISTRATE JUDGE HANNA

SECOND AMENDED COMPLAINT

Plaintiffs Abelardo DeJesus, Jr. and Desiree DeJesus, (alternatively referred to as "Plaintiff"), by and through the undersigned attorneys, hereby amend the original and First Amended Complaints in this action against Defendants Takeda Pharmaceuticals America, Inc. (hereinafter "Takeda America"), Takeda Pharmaceuticals U.S.A, Inc. (formerly known as Takeda Pharmaceuticals North America, Inc.) (hereinafter "Takeda U.S.A."), Takeda Global Research & Development Center, Inc. (hereinafter "Takeda Global") and Takeda Pharmaceutical Company Limited (hereinafter "Takeda Limited") and Takeda Pharmaceuticals LLC and Takeda Pharmaceuticals International Inc. ("Takeda International"), and Takeda California, Inc. (formerly known as Takeda San Diego, Inc.) (hereinafter "Takeda California") (collectively "Takeda" or "Defendants") and Eli Lilly and Company ("Lilly" or collectively with Takeda as "Defendants") and as for his/her First Amended Complaint alleges, upon information and belief and based on the investigation to date of counsel, as follows:

INTRODUCTION

1. This is a personal injury/product liability action brought for injuries of the Plaintiff Abelardo DeJesus, Jr. and loss of consortium on behalf of Plaintiff's spouse, Desiree DeJesus. This action is against the Defendants who were responsible for designing, manufacturing, distributing,

and/or selling the prescription drug Pioglitazone. The brand name for Pioglitazone is Actos. Actos is sold in multiple formulations known as Actos, Actoplus MET, Actoplus MET XR, or Duetact (all drug names and formulations hereinafter referenced as "Actos"). Actos is a diabetes medication used by Plaintiff Abelardo DeJesus, Jr. to improve blood sugar (glucose) control and as a result of his ingestion of Actos, Plaintiff developed bladder cancer and coronary artery disease.

2. Defendants failed to adequately warn Plaintiff or his treating physicians and healthcare providers that there is a reasonable association of Actos to bladder cancer and heart damage.

3. Defendants have concealed, and continue to conceal, from Plaintiff, his treating physicians and healthcare providers, Defendants' knowledge of Actos' propensity to cause bladder cancer and heart damage.

4. Had Plaintiff or his treating physicians been warned that there was a reasonable association that Actos can cause bladder cancer, Plaintiff, individually or through his treating physicians, would have chosen safer, alternative medicines which are effective at treating Type 2 diabetes without an increased risk of serious, deadly adverse events, including bladder cancer and heart damage.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiffs exceeds $75,000.00, exclusive of interest and costs, and because complete diversity exists between the parties, as set forth below, Plaintiffs are citizens of states that are different from the states where the Defendants are incorporated and have their principal place of business.

6. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

7. This claim was originally filed in the United States District as Court, Southern District of Florida, where venue was proper pursuant to 28 U.S.C. § 1391, and was transferred to this District by the United States Judicial Panel on Multidistrict Litigation under MDL No. 2299 Conditional Transfer Order CTO-13, dated April 4, 2012.

8. Venue is also proper within this District pursuant to 28 U.S.C. § 1391 because it is a judicial district where Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. § 1391, and is subject to Multi-District Litigation proceedings within this District as part of MDL No. 6:11-md-2299 as directed by this Court's First General Order dated January 23, 2012.

PLAINTIFF(S)

9. Plaintiff, Abelardo DeJesus, Jr., is a natural person and a resident of Miami, Florida and ingested prescription Actos as prescribed and directed by his physician and suffered from bladder cancer which was diagnosed on or around January 2004 for which treatment continued for over a year with continual follow-up care to this day.

10. Plaintiff, Desiree DeJesus, is the spouse of Plaintiff Abelardo DeJesus, Jr. and also resides in Miami, Florida.

11. Plaintiff Abelardo DeJesus, Jr. was injured as a result of his use of Actos, and therefore seeks damages for pain and suffering, ascertainable economic losses, attorneys' fees, reimbursement of cost of obtaining Actos, reimbursement for all past, present, and future health and medical care costs related to Actos.

12. Plaintiff Desiree DeJesus was deprived of the care, consideration, compassion, consortium and concern of Plaintiff Abelardo DeJesus, Jr., and has suffered injuries and damages thereby.

DEFENDANTS

13. Upon information and belief, Takeda America, is a Delaware corporation with its

principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

14. Takeda America is a wholly-owned subsidiary of Takeda Pharmaceuticals U.S.A., Inc., and is involved in the research, development, manufacturing, sales, and marketing of Actos and pioglitazone hydrochloride.

15. Takeda America has transacted and conducted business within the State of Florida and this district.

16. Takeda America has derived substantial revenue from goods and products used in the State of Florida and this district.

17. Takeda America expected or should have expected their acts to have consequences within the State of Florida, and derived substantial revenue from interstate commerce.

18. Upon information and belief, Takeda U.S.A. is a Delaware corporation with its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

19. Takeda U.S.A. is involved in the research, development, manufacturing, sales, and marketing of Actos and pioglitazone hydrochloride.

20. Takeda U.S.A. is a wholly-owned subsidiary of Takeda Limited.

21. Takeda U.S.A. has transacted and conducted business within the State of Florida and this district.

22. Takeda U.S.A. has derived substantial revenue from goods and products used in the State of Florida and this district.

23. Takeda U.S.A. expected or should have expected their acts to have consequences within the State of Florida and this district, and derived substantial revenue from interstate commerce.

24. Upon information and belief, Takeda Global is an Illinois corporation with its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

25. Takeda Global is involved in the research, development, manufacturing, sales, and marketing of Actos and pioglitazone hydrochloride.

26. Takeda Global is a wholly-owned subsidiary of Takeda North America.

27. Takeda Global has transacted and conducted business within the State of Florida and this district.

28. Takeda Global has derived substantial revenue from goods and products used in the State of Florida and this district.

29. Takeda Global expected or should have expected their acts to have consequences within the State of Florida and this district, and derived substantial revenue from interstate commerce.

30. Upon information and belief, Takeda Limited is a foreign corporation with its principal place of business located at 1-1 Doshomachi 4-chome, Chuo-Ku Osaka, 540-8645, Japan.

31. Takeda Limited is the parent/holding company of Takeda International, Takeda U.S.A., Takeda Global, and Takeda California.

32. Takeda Limited is involved in the research, development, manufacturing, sales and marketing of Actos and pioglitazone hydrochloride.

33. Upon information and belief, and at all relevant times, Takeda Limited exercised and exercises dominion and control over Defendants Takeda International, Takeda U.S.A., Takeda Global, Takeda America, and Takeda California.

34. Upon information and belief, Takeda California, Inc. (formerly known as Takeda

San Diego, Inc.), is a Delaware corporation with its principal place of business at 10410 Science Center Drive, San Diego, California 92121.

35. Takeda California is the entity resulting from the merger of Takeda San Diego, Inc., and Takeda San Francisco, Inc.

36. Takeda California is involved in the research, development, manufacturing, sales and marketing of Actos and pioglitazone hydrochloride.

37. Takeda California is a wholly-owned subsidiary of Takeda North America.

38. Takeda California has transacted and conducted business within the State of Florida and this district.

39. Takeda California has derived substantial revenue from goods and products used in the State of Florida and this district.

40. Takeda California expected or should have expected their acts to have consequences within the State of Florida and this district, and derived substantial revenue from interstate commerce.

41. Upon information and belief, Takeda International is an Illinois corporation with its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

42. Takeda International is involved in the research, development, manufacturing, sales and marketing of Actos and pioglitazone hydrochloride.

43. Takeda International has transacted and conducted business within the State of Florida and this district.

44. Takeda International has derived substantial revenue from goods and products used in the State of Florida and this district.

45. Takeda International expected or should have expected their acts to have

consequences within the State of Florida and this district, and derived substantial revenue from interstate commerce.

46. Upon information and belief, Eli Lilly and Company (hereinafter "Lilly") is an Indiana corporation with its principal place of business located at located at Lilly Corporate Center, Indianapolis, Indiana 46285.

47. Lilly was involved in the research, development, manufacturing, sales and marketing of Actos and pioglitazone hydrochloride in the United States until April 20, 2006.

48. Lilly has transacted and conducted business within the State of Florida and this district.

49. Lilly has derived substantial revenue from goods and products used in the State of Florida and this district.

50. Lilly expected or should have expected their acts to have consequences within the State of Florida and this district, and derived substantial revenue from interstate commerce.

51. Takeda Pharmaceuticals America, Inc., Takeda Pharmaceuticals U.S.A., Inc., Takeda Global Research & Development Center, Inc., Takeda Pharmaceuticals International, Inc., Takeda California, Inc., and Takeda Pharmaceutical Company Limited, and Lilly are hereinafter collectively referred to as "Defendants."

SUMMARY OF THE CASE

52. Defendants are in the business of researching, designing, developing, licensing, manufacturing, packaging, labeling, marketing, distributing and selling Actos and pioglitazone containing medicines including Actoplus Met, Actoplus Met XR, and Duetact (hereinafter collectively referred to as "Actos"), which are prescription medicines for the treatment of type 2 diabetes.

53. As a result of the defective nature of Actos, persons who were prescribed and ingested this product, including Plaintiff, have suffered and may continue to suffer from bladder cancer and heart damage.

54. Defendants failed to warn Plaintiff or his treating physicians and healthcare providers, including his prescribing physicians and healthcare providers, that Actos can cause bladder cancer and heart damage.

55. Defendants have concealed, and continue to conceal, from Plaintiff and his prescribing physicians Defendants' knowledge of Actos' propensity to cause bladder cancer and heart damage.

56. As a foreseeable, direct, and proximate result of Defendants' tortious conduct, Plaintiff was caused to suffer bladder cancer and heart damage.

57. Had Plaintiff's physicians and Plaintiff been adequately warned of the potential life-threatening side effects of the Defendants' Actos, Plaintiff's physicians would have changed the manner in which they prescribed Actos, including but not limited to, passing on the risks to the Plaintiff and discussing the risks with Plaintiff; Plaintiff would not have purchased or taken Actos and would have chosen to request other treatments or prescription medications had he been informed of the risks of Actos.

58. As a result of Defendants' actions and inaction, Plaintiff was injured due to his ingestion of Actos, which caused and will continue to cause Plaintiff's injuries and damages. Plaintiffs accordingly seeks damages associated with these injuries.

FACTUAL ALLEGATIONS

59. Defendants, directly or through their agents, designed, manufactured, marketed, advertised, distributed, promoted and sold Actos for the treatment of type 2 diabetes.

60. According to the American Diabetes Association, type 2 diabetes is the most common form of diabetes. Type 2 diabetes develops when the body does not produce enough insulin or doesn't efficiently use the insulin that it does produce. Type 1 diabetes occurs when the body does not produce any insulin at all. Insulin is necessary for the body to be able to use glucose for energy.

61. Actos was jointly launched by Takeda U.S.A. and Lilly in 1999, and Actos was approved by the Food and Drug Administration ("FDA") in July of 1999 to treat type 2 diabetes.

62. Actos is in a class of insulin-sensitizing diabetes agents known as thiazolidinediones ("TZD"s).

63. Actos exerts its antihyperglycemic effect only in the presence of endogenous insulin. Therefore, Actos is only used to treat type 2 diabetes.

64. Actos is sold as a single ingredient product under the brand name Actos, and it is also sold in combination with metformin (Actoplus Met, Actoplus Met XR) and in combination with glimepiride (Duetact), collectively referred to as Actos or pioglitazone.

65. Prior to applying for and obtaining FDA approval to market Actos, Defendants knew or should have known that Actos could cause heart damage.

66. Numerous studies have examined the effect of Actos on congestive heart failure, weight gain, edema, storage of fat, revascularization, and other cardiac effects which have shown a clear association with such events and Actos. Defendants failed to include appropriate information regarding Actos and these cardiovascular effects in its label. Defendants failed to include information regarding congestive heart failure until forced to do so by the FDA in 2007. Despite the warning, Defendants have promoted and continued to promote Actos as cardioprotective.

67. Prior to obtaining marketing authority for Actos, Defendants knew or should have known that Actos could cause bladder cancer.

68. Prior to obtaining marketing authority for Actos, Defendants conducted non-clinical experiments including a two-year carcinogenicity study on male and female rats. Drug-induced bladder tumors were observed in male rats receiving doses of Actos that produced blood drug levels equivalent to those resulting from a clinical dose.

69. Defendants conducted the PROactive (PROspective PioglitAzone Clinical Trial In MacroVascular Events) clinical trial between 2001 and 2004. PROactive prospectively looked at the impact of Actos use in total mortality and macrovascular morbidity in high risk patients. The results PROactive were published in 2005. Dormandy J.A., et al., *Secondary Prevention of Macrovascular Events in Patients with Type 2 Diabetes in the PROactive Study (PROspective PioglitAzone Clinical Trial In MacroVascular Events): a Randomised Controlled Trial*, Lancet, 266:1279-1286 (2005) ("Dormandy paper").

70. The PROactive study was designed to evaluate cardiovascular events and Outcomes, but failed to meet its primary endpoint of demonstrating any cardiovascular benefit. However, the study demonstrated a higher percentage of bladder cancer cases in patients receiving Actos versus comparators.

71. During the course of monitoring the study, the researchers and Defendants became aware that there were a statistically significant demonstrated higher percentage of bladder cancer cases in patients receiving Actos versus comparators.

72. Neither during the study, nor in the actual final Dormandy paper, did the

researchers or Defendants publish these statistically significant increases of bladder cancer. Rather, Defendants and researchers intentionally skewed the study findings to obscure the statistical significance of the bladder cancer diagnoses.

73. Defendants willfully, wantonly and with malice withheld the knowledge of the increased risk of bladder cancer in users of Actos seen in the PROactive study.

74. A three-year liver safety study also demonstrated a higher percentage of bladder cancer cases in patients receiving Actos versus comparators.

75. On April 20, 2006, Takeda Limited announced the conclusion of its collaboration in the United States between Takeda U.S.A. and Lilly to promote and market Actos, a partnership Takeda Limited described as a "great success" and "mutually beneficial to both companies."

76. On September 17, 2010, the FDA issued a Safety Announcement stating it was undertaking a review of the data from an ongoing, ten-year epidemiological study being conducted by Kaiser Permanente to evaluate the association between Actos and bladder cancer. The planned five-year interim analysis demonstrated that the risk of bladder cancer increases with increasing dose and duration of Actos use.

77. Despite the FDA finding that Actos is linked to a statistically significant increase in risk for developing bladder cancer, Robert Spanheimer, Vice President of Medical and Scientific Affairs for Takeda Limited, claimed to Reuters that the Kaiser Permanente study does not show that Actos users are at an increased risk of bladder cancer or other cancers.

78. In early 2011, the American Diabetes Association published Piccinni, et al., *Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting*, Diabetes Care, 34:1369-1371 (June 2011), published ahead of print April 22, 2011.

This study analyzed adverse events reports made to the FDA between 2004 and 2009. The conclusion of the study was that "[i]n agreement with preclinical and clinical studies, AERS analysis is consistent with an association between pioglitazone and bladder cancer. This issue needs constant epidemiologic surveillance and urgent definition by more specific studies."

79. On June 9, 2011, the European Medicines Agency announced that it had been informed by the French Medicines Agency of its decision to suspend the use of pioglitazone containing medicines (Actos, Competact) in France while awaiting the outcome of an ongoing European review.

80. France's decision was based upon a retrospective cohort study in France using the French National Health Insurance Plan which demonstrated a statistically significant increase in the risk for bladder cancer in males exposed to Actos for more than one year. The French cohort included 1.5 million patients with diabetes that were followed for four years (2006-2009).

81. On June 10, 2011, Reuters published that Germany had joined France in suspending the use of Actos after Germany's Federal Institute for Drugs and Medical Devices reviewed the results of the French study and recommended that doctors not put new patients on pioglitazone.

82. On June 15, 2011, the FDA issued a Safety Announcement stating that "use of the diabetes medication Actos (Pioglitazone) for more than one year may be associated with an increased risk of bladder cancer." The FDA ordered information about this risk to be added to the Warnings and Precautions section of the label for pioglitazone-containing medicines. The FDA further recommended that healthcare physicians discontinue use in patients with active bladder cancer.

83. On June 17, 2011, Health Canada Press Release indicated that in light of studies suggesting an increased risk of bladder cancer with the diabetes drug pioglitazone, as well as actions taken by other regulatory agencies, Health Canada informed healthcare professionals and Canadians that it was undertaking a review of the drug's status.

84. On July 12, 2011, Takeda Limited issued a recall of Actos in France.

85. As the manufacturers of Actos, Defendants knew or should have known that Actos usage was associated with an increased risk of bladder cancer as well as heart damage.

86. Despite their knowledge prior to obtaining marketing authority that Actos use was associated with an increased risk of bladder cancer and heart damage, Defendants failed to warn consumers, including Plaintiff herein, and prescribing physicians of the true and significant risk of bladder cancer and promoted Actos as cardioprotective when in fact Actos causes heart damage.

87. Despite their knowledge of the results of medical studies and analyses which found statistically significant elevations in the incidences of bladder cancer in individuals exposed to Actos therapy, Defendants refused to warn consumers, including Plaintiff, prescribing physicians, including Plaintiff's physicians, and the general public of the true and significant risk of bladder cancer associated with Actos therapy. Instead, Defendants promoted Actos as a safe and effective treatment for type 2 diabetes.

88. Despite their knowledge of the results of medical studies and analysis which showed that Actos causes heart damage, Defendants refused to warn consumers, including Plaintiff, prescribing physicians, including Plaintiff's prescribing physicians, and the general public of the true and significant risk of heart damage associated with Actos therapy. Instead, Defendants promoted Actos as cardioprotective.

89. By failing to warn that Actos was and is associated with a true and significant increased risk of bladder cancer and heart damage, Defendants' marketing efforts succeeded in making Actos the top-selling pharmaceutical for Defendants. In 2008, Actos was the tenth bestselling medication in the United States.

90. Defendants, through their affirmative misrepresentations and omissions, have actively concealed and continue to conceal from consumers, including Plaintiff, and prescribing physicians, including Plaintiff's prescribing physicians, the true and significant risk of injuries caused by Actos exposure.

91. As a result of Defendants' actions, Plaintiff and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

92. Defendants have yet to adequately warn consumers and the prescribing medical community about the true and significant risks of bladder cancer associated with Actos use.

93. Defendants continue to promote Actos as cardioprotective despite knowing that Actos causes heart damage.

94. As a result of the defective nature of Actos, persons who were prescribed and ingested Actos, including Plaintiff, were exposed to an increased risk for developing bladder cancer and heart damage, have been diagnosed with bladder cancer and/or heart damages, and fear the recurrence of their injuries.

95. In or around October 2002, Plaintiff was prescribed and began taking Actos. Plaintiff subsequently developed bladder cancer in January of 2004. Plaintiff was continued to

be prescribed Actos from 2004 – 2008 and Plaintiff developed coronary artery disease requiring CABG surgery in 2008.

96. Had Plaintiff's physicians and Plaintiff been adequately warned of the potential life-threatening side effects of the Defendants' Actos, Plaintiff's physicians would have changed the manner in which they prescribed Actos, including but not limited to, passing on the risks to the Plaintiff and discussing the risks with Plaintiff; Plaintiff would not have purchased or taken Actos and would have chosen to request other treatments or prescription medications had he been informed of the risks of Actos.

97. Numerous, alternative, safer products are available to treat type 2 diabetes.

98. Without accurate and complete information regarding Actos' serious side effects and lack of benefits, Plaintiff, individually or through his prescribing physicians, was not able to perform a risk/benefit analysis regarding Actos treatment versus other available diabetes treatments.

99. Plaintiff would not have used Actos had Defendants properly disclosed the risks associated with its use.

100. As a direct result of the defective nature of Actos, Plaintiffs have been permanently and severely injured, having suffered serious consequences from Actos use. Plaintiff requires and will in the future require ongoing medical care and treatment.

101. As a direct and proximate result of Defendants' tortious conduct and the unreasonably dangerous and defective characteristics of Actos, Plaintiff suffered severe and permanent physical injuries, including bladder cancer, as well as the need for revascularization. Plaintiff has endured and continues to endure substantial pain and suffering. Plaintiffs have incurred expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiffs have suffered and will continue to suffer economic loss. Plaintiffs have suffered

and continue to suffer emotional distress associated with the diagnosis of cancer and resulting from the fear of the recurrence of the cancer, malignancies, and future treatment options, including removal of the urinary bladder. Plaintiffs seek damages in excess of $75,000.00, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deems proper.

FIRST CAUSE OF ACTION
(NEGLIGENCE)

102. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

102. Defendants had a duty to Plaintiffs to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Actos and pioglitazone hydrochloride into the stream of commerce, including a duty to assure that Actos and pioglitazone hydrochloride would not cause users to suffer unreasonable, dangerous side effects such as cancer.

103. Defendants failed to exercise ordinary care and/or were reckless in designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Actos into interstate commerce in that Defendants knew or should have known that using Actos caused a risk of unreasonable, dangerous side effects, including bladder cancer.

104. Despite the fact that Defendants knew or should have known that Actos was associated with and/or caused bladder cancer, Defendants continued to market, manufacture, distribute and/or sell Actos to consumers, including the Plaintiff.

105. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

106. Defendants' negligence and/or recklessness were the legal and proximate cause of Plaintiff's injuries, harm and economic loss which he suffered.

107. As a result Defendants' negligence and/or recklessness Plaintiff was caused to suffer serious and dangerous side effects including bladder cancer and heart damage, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as related surgical procedures, medical treatment, monitoring and/or medications.

108. As a result of the foregoing acts and omissions, Plaintiff required health care and services and did incur medical, health, incidental and related expenses.

109. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deems proper.

SECOND CAUSE OF ACTION
(STRICT PRODUCTS LIABILITY - FAILURE TO WARN)

110. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

111. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced Actos into the stream of commerce, and in the course of same, directly advertised or marketed Actos and pioglitazone hydrochloride to consumers or persons responsible for consumers, and therefore, had a duty to both Plaintiff directly and Plaintiff's physician to warn of risks associated with the use of the product.

112. Defendants had a duty to warn of adverse drug reactions, which they know or have reason to know can be caused by the use of Actos and pioglitazone hydrochloride and/or

are associated with the use of Actos and pioglitazone hydrochloride.

113. The Actos and pioglitazone hydrochloride manufactured and/or supplied by Defendants was defective due to inadequate post-marketing warnings and/or instructions because, after Defendants knew or should have known of the risks of bladder cancer from Actos use, they failed to provide adequate warnings to consumers of the product, including Plaintiff and Plaintiff's physicians, and continued to aggressively promote Actos.

114. Due to the inadequate warning regarding bladder cancer, Actos was in a defective condition and unreasonably dangerous at the time that it left the control of Defendants.

115. Defendants failed to adequately warn Plaintiff and Plaintiff's prescribing physicians of human and animal results in preclinical studies pertaining to bladder cancer and Actos.

116. Defendants' failure to adequately warn Plaintiff and Plaintiff's prescribing physicians of a bladder cancer risk prevented Plaintiff's prescribing physicians and Plaintiff from correctly and fully evaluating the risks and benefits of Actos and pioglitazone hydrochloride.

117. Had Plaintiff been adequately warned of the potential life-threatening side effects of Defendants' Actos and pioglitazone hydrochloride, Plaintiff would not have purchased or taken Actos and could have chosen to request other treatments or prescription medications.

118. Upon information and belief, had Plaintiff's prescribing physicians been adequately warned of the potential life-threatening side effects of Defendants' Actos and pioglitazone hydrochloride, Plaintiff's prescribing physicians would have discussed the risks of bladder cancer and Actos with Plaintiff and/or would not have prescribed it.

119. As a foreseeable and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiffs were caused to suffer from the aforementioned injuries and

damages.

120. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deems proper.

THIRD CAUSE OF ACTION
(STRICT PRODUCTS LIABILITY - DEFECTIVE DESIGN)

121. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

122. Actos was expected to, and did, reach the intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which it was produced, manufactured, sold, distributed, labeled, and marketed by Defendants.

123. At all times relevant, Actos was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition, which was dangerous for use by the public, and, in particular, by Plaintiff.

124. Actos and pioglitazone hydrochloride as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants was defective in design and formulation in that when it left the hands of the manufacturers and/or suppliers the foreseeable risks exceeded the alleged benefits associated with the design and formulation of Actos.

125. Actos and pioglitazone hydrochloride as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants was defective in design and formulation, because when it left the hands of Defendants' manufacturers

and suppliers it was unreasonably dangerous and was also more dangerous than the ordinary consumer would expect.

126. At all times herein mentioned, Actos and pioglitazone hydrochloride was in a defective condition and was unsafe, and Defendants knew and had reason to know that the product was defective and inherently unsafe, especially when Actos was used in a form and manner instructed and provided by Defendants.

127. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, common, intended use.

128. At the time of Plaintiff's use of Actos, it was being used for its intended purpose, and in a manner normally intended, namely for the treatment of Type 2 Diabetes Mellitus.

129. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed a defective product that caused an unreasonable risk to the health of consumers, and to Plaintiff in particular, and Defendants are therefore strictly liable for the injuries and damages sustained by Plaintiff.

130. At the time Defendants' product left their control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Actos. This was demonstrated by the existence of other Type 2 Diabetes Mellitus medications which had a more established safety profile and a considerably lower risk profile.

131. Plaintiff could not, by the reasonable exercise of care, have discovered Actos's defects and perceived its danger.

132. The defects in Defendants' product were substantial and contributing factors in causing Plaintiff's injuries.

133. As a foreseeable, direct, legal, and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiffs were caused to suffer from the

aforementioned injuries and damages.

134. Due to the unreasonably dangerous condition of Actos, Defendants are strictly liable to Plaintiff.

135. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deems proper.

FOURTH CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY)

136. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

137. Defendants expressly warranted that Actos was safe for its intended use and as otherwise described in this complaint. Actos did not conform to these express representations, including, but not limited to, the representation that it was well accepted in patient and animal studies, the representation that it was safe, and the representation that it did not have high and/or unacceptable levels of life-threatening side effects like bladder cancer, that it would improve health, maintain health, and potentially prolong life.

138. The express warranties represented by the Defendants were a part of the basis for Plaintiff's use of Actos and Plaintiff relied on these warranties in deciding to use Actos.

139. At the time of the making of the express warranties, the Defendants had knowledge of the purpose for which the Actos and pioglitazone hydrochloride was to be used, and warranted same to be in all respects safe, effective and proper for such purpose.

140. Actos does not conform to these express representations because Actos is not safe or effective and may produce serious side effects, including among other things bladder cancer, degrading Plaintiff's health, and shrinking his life expectancy.

141. As a result of the foregoing breach of express warranty the Plaintiff was caused to suffer bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future cancer(s), reasonable fear of future cancer, any and all life complications caused by Plaintiff's bladder cancer, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above and other named health consequences.

142. By reason of the foregoing, Plaintiffs have been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment than prior to his use of Defendants' Actos drug.

143. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

144. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

FIFTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY FOR A PARTICULAR PURPOSE)

145. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

146. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos and pioglitazone hydrochloride, to treat Type 2 Diabetes Mellitus.

147. The Defendants impliedly represented and warranted to the users of Actos that Actos was safe and fit for the particular purpose for which said product was to be used, namely treating diabetes, improving health, maintaining health, and potentially prolonging life.

148. These representations and warranties aforementioned were false, misleading, and inaccurate in that Actos and pioglitazone hydrochloride were unsafe, degraded Plaintiff's health and shortened his life expectancy.

149. Plaintiff relied on the implied warranty of fitness for a particular use and purpose.

150. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether Actos was safe and fit for its intended use.

151. Actos and pioglitazone hydrochloride were injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

152. Defendants breached the aforesaid implied warranty, as their drug Actos was not fit for its intended purposes and uses.

153. As a result of the foregoing breach of warranty, the Plaintiff was caused to suffer serious and dangerous side effects including bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future cancer(s), reasonable fear of future cancer, any and all life complications caused by Plaintiff's bladder cancer, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above and other named health consequences.

154. As a result of the foregoing acts and omissions, the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses.

Plaintiff is informed, and believes, and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

155. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

SIXTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY)

156. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

157. Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos and pioglitazone hydrochloride, to treat Type 2 Diabetes Mellitus.

158. Defendants marketed, sold and distributed Actos and knew and promoted the use for which Actos was being used by Plaintiff and impliedly warranted to Plaintiff that Actos was of merchantable quality and fit for the ordinary purpose for which it was intended, namely treating diabetes, improving health, maintaining health, and potentially prolonging life.

159. These representations and warranties aforementioned were false, misleading, and inaccurate in that Actos and pioglitazone hydrochloride were unsafe, degraded Plaintiff's health and shortened his life expectancy.

160. Plaintiffs reasonably relied on the skill, expertise and judgment of the Defendants and its representations as to the fact that Actos was of merchantable quality.

161. The Actos and pioglitazone hydrochloride manufactured and supplied by the Defendants was not of merchantable quality, as warranted by the Defendants in that the drug had

dangerous and life threatening side effects and was thus not fit for the ordinary purpose for which it was intended.

162. As a direct and proximate result of the foregoing, Plaintiff was caused bodily injury, pain and suffering and economic loss.

163. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future cancer(s), reasonable fear of future cancer, any and all life complications caused by Plaintiff's bladder cancer, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above and other named health consequences.

164. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

165. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

166. By reason of the foregoing, Plaintiffs are entitled to compensatory and punitive damages in a sum that exceeds the jurisdictional limits of all lower courts that might otherwise have jurisdiction.

SEVENTH CAUSE OF ACTION
(FRAUD AND FRAUDULENT CONCEALMENT)

167. Plaintiffs reallege and repeat those paragraphs above as if set forth fully herein.

168. Defendants made material representations and material omissions and/or concealments to Plaintiff, his treating physicians, to the medical and healthcare community at large, and to the general public regarding the safety and/or efficacy of Actos.

169. Defendants made material representations by using written or verbal communications, advertisements, drug packaging and labeling, and/or statements made by Defendants' agents. These representations were intended to promote and/or support Actos, including, but not limited to, representations of the following effect:

a. That Actos is a safe and effective drug for use in Type 2 Diabetics;

b. That Actos was a safer and more effective drug than other Type 2 Diabetes drugs or treatments;

c. That Actos has significant or superior health benefits, especially as compared to other drugs, including but not limited to, superior lipid profile benefits, superior organ and tissue benefits, superior blood sugar control, and/or significant reduced risk for heart-related adverse events;

d. That Actos had a favorable safety profile, and had fewer adverse health and side effects than were known or should have been known by Defendants;

e. That Actos poses no statistically significant risk of cancer to the urinary tract and/or bladder in humans.

170. Defendants made these material representations, which also included omissions of material fact, to the medical and healthcare community at large, the general public, to Abelardo DeJesus' medical or healthcare provider(s), and/or to Abelardo DeJesus with intent to induce medical and healthcare providers and Type 2 Diabetes patients to dispense, provide, prescribe, accept, purchase, and/or consume the drug for treatment of Type 2 Diabetes. Specifically, but not exhaustively, Defendants made false material representations and/or material omissions through the course of an aggressive sales and marketing operation that implemented false and misleading

statements by sales representatives, Defendant-sponsored literature, and/or Defendant-sponsored promotional functions in order to promote and sell Actos while omitting material facts regarding the drug's dangerous side effects and adverse events, including evidence that Actos was associated with an increased risk of bladder cancer and heart damage.

171. Defendants knew or should have known that their representations were false or misleading and/or knew that Defendants were concealing and/or omitting material information from the medical and healthcare community at large, the general public, from Abelardo DeJesus's medical or healthcare provider(s), and/or Abelardo DeJesus.

172. In addition to making false and misleading material representations to the medical and healthcare community at large, the general public, Abelardo DeJesus' medical or healthcare provider(s), and/or Abelardo DeJesus, Defendants also fraudulently concealed and/or intentionally omitted material information, including, but not limited to, the following:

a. That Actos was not as safe as other Forms of Type 2 diabetes treatments or drugs;

b. That the risks of adverse events, including the risk of being diagnosed with bladder cancer as a result of ingesting the drug, were higher than those with other forms of Type 2 diabetes treatments;

c. That the risks of adverse events, including the risk of being diagnosed with bladder cancer as a result of ingesting the drug, were not adequately tested and/or warned of by Defendants;

d. That Actos was defective, and that it caused dangerous side effects, including being diagnosed with bladder cancer as a result of ingesting the drug, in a much higher and more significant rate than other forms of Type 2 diabetes treatments;

e. That patients needed to be monitored more regularly for adverse events, including bladder cancer, while using;

f. That Actos was designed negligently;

g. That Actos lacked sufficient warnings with regard to adverse events, including bladder cancer;

h. That Actos was designed defectively; and

i. That Actos was designed improperly.

173. Defendants also actively engaged in concealing and omitting post-market data and evidence known to Defendants while Actos was on the market that indicated that Actos was associated with an increased risk of bladder cancer in humans. Since 1999 Defendants were faced with multiple opportunities to inform the medical and healthcare community at large, the general public, Plaintiff's medical or healthcare provider(s), and/or Plaintiff of the risks and dangers of Actos, yet Defendants consciously and deliberately withheld, concealed, and omitted such information. Incidents in which Defendants actively engaged in concealing and omitting post-market data and evidence include, but are not limited to:

a. After the release of Actos onto the market, Defendants were informed that other Type 2 diabetes drugs, compounds, or formulations in the same or substantially similar class of drugs as Actos were associated with an increased risk of bladder cancer, yet Defendants engaged in a course of conduct to actively ignore, separate, and or disassociate Actos from being associated with any drug, compound, or formulation with an increased risk of bladder cancer without an adequate scientific or pharmacological basis for such ignorance, separation, or disassociation;

b. After the release of Actos onto the market, Defendants possessed facts and evidence that indicated that Actos was associated with an increased risk of bladder cancer in humans, and were faced with several opportunities, including suggestions from the Food and Drug Administration (FDA), to revise the packaging and/or labeling of Actos to strengthen its warnings with regard to an increased risk of bladder cancer. Not only did Defendants decline to strengthen Actos' packaging and/or labeling to inform medical and health care providers and consumers, but Defendants engaged in a false and misleading marketing and regulatory plan and/or process to aggressively combat any suggestions by regulatory and/or medical authorities that the Actos label should be revised. Defendants' plan and/or process to combat label changes through false and misleading means was often predicated upon Defendants' concerns regarding the negative sales and marketing ramifications of a label change, as opposed to patient safety;

c. After the release of Actos onto the market, Defendants possessed clinical data through studies, including Defendant-sponsored studies, that Actos was associated with a statistically significant increased risk of bladder cancer in humans. After receiving this information, Defendants engaged in false and or misleading conduct and intentionally withheld, suppressed, misrepresented, and/or concealed this data from the medical and healthcare community at large, the general public, Plaintiff's medical or healthcare provider(s), and/or Plaintiff Abelardo DeJesus, Jr.

d. Upon hearing any negative news about its competitors, such as the GlaxoSmithKline drug Avandia, Defendants conducted aggressive marketing campaigns against such

competitors touting the alleged benefits of Actos over its competitor while purposefully and knowingly suppressing information about life-threatening side effects of Actos such as the increased risk of bladder cancer.

174. Defendants had sole access to material facts concerning the defective nature of Actos and its propensity to cause serious and dangerous side effects, including bladder cancer and heart damage, to persons who used Actos, including Plaintiff.

175. Defendants' misrepresentations, concealments and omissions of material facts were made purposefully, willfully, wantonly, and/or recklessly in order to mislead and to induce Plaintiff's prescribing physicians to prescribe and/or dispense Actos and to induce Plaintiff to purchase and consume Actos.

176. Plaintiff's treating physicians and Plaintiff had no way to determine the truth behind Defendants' false and/or misleading statements, concealments and omissions surrounding Actos, and reasonably relied on false and/or misleading facts and information disseminated by Defendants, which included Defendants' omissions of material facts in which Plaintiff's treating physicians and Plaintiff had no way to know were omitted.

177. Plaintiff's treating physicians and Plaintiff justifiably relied on the false and/or misleading statements made by Defendants and relied on Defendants' statements without knowledge of the falsity of the statements and the omissions of material facts contained therein. Defendants were in a position to disseminate information regarding the efficacy and safety of Actos and Plaintiff's treating physicians and Plaintiff was, justifiably, placed in a position to receive and rely on this information in considering whether to prescribe and/or consume Actos.

178. Plaintiff's treating physicians and Plaintiff justifiably relied upon Defendants' material misrepresentations, including the omissions contained therein, when making the decision to dispense, provide, prescribe, accept, purchase, and/or consume Actos. Defendants, as was intended by their material misrepresentations and omissions, induced Plaintiff and prescribing physicians to dispense, provide, prescribe, accept, purchase, and/or consume Actos.

179. As a direct and proximate result of the above-stated false representations and/or omissions as described herein, Plaintiffs were injured as described above.

180. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

181. By reason of the foregoing, Plaintiffs are entitled to compensatory and punitive damages in a sum that exceeds the jurisdictional limits of all lower courts that might otherwise have jurisdiction.

EIGHTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION)

182. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

183. During the course of business dealings with Plaintiff and Plaintiff's physicians, Defendants disseminated false information, through literature, published labels and otherwise, concerning the properties and effects of Actos with the intention that physicians and patients would rely upon that information in their decisions concerning the prescription and consumption of drug therapy for their patients.

184. Defendants, as prescription drug manufacturers and/or distributors, disseminated information about Actos in order to guide Plaintiff and Plaintiff's physicians in the business transaction of the sale and purchase of prescription drugs. Defendants knew or reasonably should have realized that physicians, in weighing the potential benefits and potential risks of using Actos, would rely upon information disseminated to them by the manufacturer and/or distributor of the product, and that many patients, in accordance with those prescriptions, would be likely to ingest Actos as properly dispensed by their pharmacies.

185. Defendants, as prescription drug manufacturers and/or distributors, knew or reasonably should have realized that patients receiving prescriptions for Actos, written by physicians in reliance upon information disseminated by Defendants as the manufacturer/distributor of Actos, would be placed in peril of grievous personal injury if the information disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

186. Defendants failed to exercise reasonable care or competence to ensure that the information it disseminated to physicians concerning the properties and effects of Actos was accurate and not misleading, and, as a result, disseminated information to physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff.

187. Plaintiff's prescribing physicians and Plaintiff had no way to determine the truth behind Defendants' false representations and omissions surrounding Actos, and reasonably relied on false and/or misleading facts and information disseminated by Defendants, which included Defendants' omissions of material facts in which Plaintiff's prescribing physicians and Plaintiff had no way to know were omitted.

188. Plaintiff's prescribing physicians and Plaintiff justifiably relied on the false and/or misleading statements made by Defendants and relied on Defendants' statements without knowledge of the falsity of the statements and the omissions of material facts contained therein. Defendants were in a position to disseminate information regarding the efficacy and safety of Actos and Plaintiff's prescribing physicians and Plaintiff were, justifiably, placed in a position to receive and rely on this information in considering whether to prescribe and/or consume Actos.

189. As a direct and proximate result of the above-stated false representations and/or omissions as described herein, Plaintiff suffered serious and dangerous side effects including Bladder Cancer, as well as other severe and personal injuries which are permanent and lasting in

nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future cancer(s), reasonable fear of future cancer, any and all life complications caused by Plaintiff's Bladder Cancer, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above.

190. By reason of the foregoing, Plaintiffs demand judgment against Defendants for damages in a sum in excess of $75,000.00, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deems proper.

NINTH CAUSE OF ACTION
VIOLATION OF CONSUMER FRAUD AND
STATE DECEPTIVE TRADE PRACTICE LAWS

191. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

192. Defendants committed deceptive trade practices by knowingly making false representations and omitting and concealing material information regarding Actos' characteristics and alleged benefits and failing to disclose material information regarding known risks, including bladder cancer to Plaintiff and Plaintiff's Physician while manufacturing, distributing, and/or selling Actos for purchase and consumption by consumers, including Plaintiff.

193. Defendants' actions are deceptive and in clear violation of FDUTPA, entitling Plaintiffs to damages and relief under Fla. Stat. §§ 501.201-213.

194. Plaintiff was a consumer within the meaning of FDUTPA, who was deceptively and unlawfully induced to purchase Actos by Defendants.

195. Florida Statutes, Section 501.204 makes unfair and/or deceptive trade practices in the conduct of any trade or commerce illegal.

196. Florida Statutes, Section 501.211 creates a private right of action for

individuals who are aggrieved by an unfair and/or deceptive trade practice by another person.

197. Florida Statutes, Section 501.2105 provides that the prevailing party in litigation arising from a cause of action pursuant to Chapter 501 shall be entitled to recover attorney's fees within the limitations set forth therein form the non-prevailing party.

198. Florida Statutes, Section 501.213 provides that any remedies available under Chapter 501 are in addition to any other remedies otherwise available for the same conduct under state or local law.

199. Florida Statutes, Section 501.203 (3)(c) states that a person has violated the Florida Deceptive and Unfair Trade Practices Act if he violates "any law, statute, rule, regulation, or ordinance which proscribes unfair, deceptive, or unconscionable acts or practices."

200. Defendants are engaged in the practice of manufacturing, marketing, distributing, selling and otherwise placing into the stream of commerce Actos which constitutes trade and commerce as defined by Sections 501.203(8) Fla. Stat., and is therefore subject to FDUPTA.

201. Defendant's acts constitute unconscionable, deceptive, or unfair acts or practices in violation of FDUTPA.

202. As a result of Defendants' unfair and deceptive trade practices, Plaintiffs are entitled to an award of attorney's fees pursuant to FDUTPA, Florida Statutes, Section 501.2105, if he prevails.

203. WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

TENTH CAUSE OF ACTION
(LOSS OF CONSORTIUM)

195. Plaintiffs incorporate by reference each and every prior and subsequent allegation of this complaint as if fully restated here.

196. Plaintiff Desiree DeJesus was and is the lawful spouse of Plaintiff Abelardo DeJesus, Jr., and as such, was and is entitled to the comfort, enjoyment, society and services.

197. As a direct and proximate result of the foregoing, Plaintiff Desiree DeJesus was deprived of the comfort and enjoyment of the services and society of her spouse and has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured. Plaintiff Desiree DeJesus' injuries and damages are permanent and will continue into the future. The Plaintiffs seek compensatory and punitive damages from the Defendant as alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiffs for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiffs, health care costs, medical monitoring, together with interest and costs as provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding Plaintiffs' attorney's fees;

4. Awarding Plaintiffs' the costs of these proceedings; and

5. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury as to all issues.

Dated: April 30, 2013.

By: /s/ Neil D. Overholtz
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